

REMARKS

Claims 1, 45, and 55 are currently under consideration. Claims 2-44, 46-48, 50-54, and 56-65 have been previously withdrawn. Claim 49 was previously cancelled. In the current Office Action, the Office also withdrew claims 66-67, which are discussed below. No amendments to the claims have been made in this reply. Applicants address below each issue raised in the Office Action (“Action”) of April 14, 2008.

Restriction of Claims 66-67

In the prior response, Applicants added new claims 66-67, which are directed to a method of modulating the differentiation and/or metabolism in an adipocyte, which comprises contacting the adipocyte with a protein comprising the amino acid sequence of SEQ ID NO:2 or salt thereof (claim 66) and to a method for screening a compound or salt thereof that modulates the differentiation of and/or metabolism in an adipocyte, which also comprises contacting a test compound with a protein comprising the amino acid sequence of SEQ ID NO: 2 (claim 67). The Office has withdrawn claims 66-67 from consideration, as being “drawn to a non-elected invention.” Action at page 2-3. The Office contended that “the elected claims 1, 45 and 55 relate to claims 66-67 as product and process of use.” Action at page 2. Because the claimed product allegedly “can be utilized in a materially different processes,” the Office found that claims 66-67 are patentably distinct from the elected invention of claims 1, 45, and 55 under M.P.E.P. § 806.05(h). Action at pages 2-3.

Applicants respectfully traverse. According to M.P.E.P. § 803, two requirements must be met before a proper restriction requirement may be made: (1) the inventions must be independent or distinct as claimed; and (2) there must be a serious burden on the Examiner if

restriction is not required. Applicants respectfully submit that the Office has failed to establish both requirements of M.P.E.P. § 803.

In the present invention, claims 1, 45, and 55 are drawn to an isolated protein and a composition and kit thereof. Claims 66-67 are directed to methods for using the same isolated protein. A search and examination of the subject matter of claims 1, 45, and 55 would encompass a search for the subject matter of claims 66-67, and any additional search would not impose a serious burden upon the Examiner. Thus, Applicants respectfully request that claims 1, 45, 55 and 66-67 be examined together. In the event that the restriction requirement is maintained, Applicants reserve the right to file divisional applications on non-elected inventions and/or to request rejoinder of appropriate claims once the subject matter of claims 1, 45, and 55 is found allowable.

Rejections Under 35 U.S.C. § 101

The Office rejected claims 1, 45, and 55 under 35 U.S.C. § 101 because allegedly “the claimed invention is not supported by either a well-established or disclosed specific and substantial credible utility.” Action at page 4. The Office asserts that the restricted and regulated expression of the SST20-14 protein does not lend specific utility because “specific ‘gene expression’ may not reflect the function and usefulness *per se* of the protein which is the product of said gene expression.” Action at page 4. With regard to the ability of the SST20-14 to bind the lipid moiety of lipoprotein, the Office contends that “binding to lipid moiety of a lipoprotein cannot be considered specific” and that the protein’s lipoprotein-binding motif is inadequately defined. Action at page 5. In addition, the Office alleges that the SST20-14 protein is not supported by substantial utility because “the specification does not teach direct use of the claimed protein to treat a condition or disease or applied to a biological event having substantial

utility.” Action at page 5. Although induced insulin resistance depresses SST20-14 gene expression, the Office contends that the specification (1) does not establish a connection between insulin resistance and the protein itself, and (2) does not “disclose the core sequence(s) or domain(s) critical for biological function” of the protein. Action at pages 5-6. Applicants respectfully disagree.

Applicants need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. § 101 (and 35 U.S.C. § 112, discussed below). *See e.g., Ratheon v. Roper*, 724 F.2d 951, 958 (Fed. Cir. 1983); MPEP § 2107.02. The claimed invention is directed to an isolated protein comprising the amino acid sequence SEQ ID NO: 2 or a salt thereof, which is also referred to in the specification as SST20-14 (long form), and a composition or a kit comprising the protein. Applicants respectfully assert that the claimed invention has specific and substantial utility for influencing adipocyte development. The invention provides one skilled in the art with the means to inhibit differentiation of precursor cells into mature adipocytes. *See* Specification at pages 149-50. Transfection of 3T3-L1 preadipocytes with an SST20-14 (long form) expression construct before chemically inducing differentiation, reduced lipid drop accumulation to “half or less” as compared to non-transfected 3T3-L1 cells. Specification at pages 149-50. Thus, one skilled in the art could deliver SST20-14 protein or compositions thereof to adipocytes or adipose tissue in order to reduce proliferation of mature white adipocytes.

Because excess fat is associated with human health disorders including diabetes, arteriosclerosis, and hypertension, Specification at page 1, the SST20-14 protein provides an attractive avenue toward treating such diseases by impeding the underlying fat accumulation. According to M.P.E.P. § 2107.01, the identification of a pharmacological activity relevant to an

asserted pharmacological use for a compound necessarily satisfies the utility requirement. Furthermore, though the Office acknowledges support in the specification for the use of the claimed invention to suppress differentiation of precursor adipocytes, Action at page 4, nowhere does the Office consider or controvert the specificity, substance, or credibility of this use. As such, Applicants respectfully assert that the Office has not met its burden to establish a *prima facie* showing that the current invention lacks utility as specified in M.P.E.P. § 2107.02.

Accordingly, Applicants respectfully traverse the rejections under § 101 and request their reconsideration and withdrawal.

Rejections Under 35 U.S.C. § 112, First Paragraph

The Office has rejected claims 1, 45, and 55 under 35 U.S.C. § 112, first paragraph, because the claimed invention allegedly was not supported by a substantial, specific, or well-established asserted utility such that one skilled in the art would not know how to use the claimed invention without undue experimentation. Action at page 7.

For the reasons advanced concerning the § 101 rejection, Applicants respectfully assert that the claimed invention has a substantial and specific utility. Again, the specification teaches one skilled in the art that the SST20-14 protein is useful for inhibiting adipocyte maturation. In view of this detailed disclosure, one skilled in the art would not require undue experimentation to use the claimed invention. Therefore, withdrawal of the rejection is respectfully requested.

In view of the foregoing remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: August 13, 2008

By: Yuko Soneoka
Yuko Soneoka
Reg. No. 60,018
(650) 849-6679